8. The soluble film preparation according to claim 1, in which the oligosaccharide is reducing maltose starch syrup.

11. The soluble film preparation according to claim 1, in which the compound is nilvadipine, the additional edible polymer is hydroxypropyl cellulose, and the starch syrup is reducing maltose starch syrup.

REMARKS

In the Office Action dated June 18, 2002, claims 1-12 are pending in the present application, and all of claims 1-12 stand rejected. Claim 12 has been cancelled. Claims 1, 4, 8, and 11 have been amended to further clarify the subject matter of the invention. No new matter has been added by virtue of the amendments because they are supported in the specification. Support for the claim amendments are found throughout the specification and the claims as filed on, e.g., on page 9, line 11 through page 10, line 14, page 12, Example 15 through and including page 13, Example 21, and Figure 1.

Applicants also submit the amendments may be properly entered at this time, i.e., after final rejection pursuant to 37 C.F.R. § 1.116 because the amendments to not raise any new issues or require a new search and they reduce the issues for appeal. For instance, the claims as amended herein are within the scope of prior searches. It is also believed the application is clearly in condition for allowance. Entry of the amendments is earnestly solicited.

Applicants respectfully request reconsideration of the application in light of the above amendments and the following discussion.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Applicants respectfully disagree with the finality of the instant Office Action because the claims are rejected therein entirely over art not of record. MPEP 706.07 (a) states in pertinent part:

> "(A) second or any subsequent action on the merits in any application or patent undergoing reexamination proceedings will not be made final if it includes a rejection, on newly cited art, other than information submitted in an information disclosure statement filed under 37 CFR (c) with the fee set forth in 37 CFR 1.17 (p), of any claim not amended by applicant or patent owner in spite of the fact that other claims may have been amended to require newly cited art. Where information is submitted in a reply to a requirement under 37 CFR 1.105, the examiner may NOT make the next Office action relying on that art final unless all instances of such art are necessitated by amendment.
>
> A second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should not be made final if it includes a rejection on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed."

The claim amendments made by way of the Response and Amendment Under 37 C.F.R. §1.111 were made within the scope of the originally examined claims and were rejected over art not previously of record. Thus, Applicants request the reconsideration and removal of the finality of the Office Action in view of the newly cited art.

Claims 1-3, 5-8, 10 and 12 are rejected under 35 U.S.C. §102(b) as anticipated by Fuchs, *et al.* (U.S. Patent No. 4,136,145, "Fuchs").

Applicants respectfully traverse this rejection. The cited reference does not teach the presently claimed soluble film preparation.

As amended, the claims are to a soluble film preparation comprising a drug, edible polymer, and either a monosaccharide or an oligosaccharide, formed into a film by spreading and drying that has an elution rate of more than about 50% per 10 minutes and the drug is a compound that forms a solid solution with the polymer to enhance internal absorption. Solid solutions of exemplary drugs and polymers that

enhance the absorption of the drugs are described in the specification on page 9, line 26 to page 10, line 14.

While Fuchs may disclose a soluble film preparation for drug delivery, nowhere in Fuchs does the disclosure teach or suggest a soluble film preparation that consists of a monolayer obtained by spreading and drawing having an elution rate of more than about 50% per 10 minutes and contains a drug and an edible polymer that forms a solid solution to enhance internal absorption of the drug.

Applicants respectfully request reconsideration and withdrawal of the rejection.

Thus, all the claims are allowable over this reference.

Claims 1-12 are rejected under 35 U.S.C. §103(a) as obvious over Fuchs, *et al.* in view of Oyangui, *et al.* ("Oyangui").

Applicants respectfully traverse this rejection. The cited references do not obviate the presently claimed soluble film preparation.

As claimed, the invention is a soluble film preparation comprising a drug, edible polymer, and either a monosaccharide or an oligosaccharide, formed into a film by spreading and drying that has an elution rate of more than about 50% per 10 minutes and the drug is a compound that forms a solid solution with the polymer to enhance internal absorption.

Oyangui does not make up for the deficiencies of Fuchs. Oyangui appears to teach the ant-inflammatory effects of nilvadipine on ischemic and carrageenan paw edema in rats and mice. Indeed, the reference does not disclose any other composition with which nilvadipine may be administered. There is no suggestion in Oyangui to use the drug nilvadipine in the composition of Fuchs to arrive at the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Thus, all the claims are allowable over these references.

Claim 12 is rejected under 35 U.S.C. §103(a) as obvious over Fuchs, *et al.*, and further in view of Terada, *et al.* (U.S. Patent No. 5,102,950, "Terada").

Applicants respectfully traverse this rejection. As amended, the claims are not obvious over the cited references.

The instant claims are directed to a soluble film preparation comprising a drug, edible polymer, and either a monosaccharide or an oligosaccharide, wherein the film is formed by spreading and drying and has an elution rate of more than about 50% per 10 minutes and wherein the drug is a compound that forms a solid solution with the edible polymer to enhance internal absorption.

As discussed above, Fuchs may disclose a soluble film preparation for drug delivery but nowhere does the reference teach or suggest a soluble film preparation formed by spreading and drawing and has an elution rate of more than about 50% per 10 minutes that contains both a drug and an edible polymer that forms a solid solution to enhance internal absorption of the drug.

Terada appears to disclose water soluble films containing a polymer that are used as packaging dry materials or liquids containing no water. (col. 9, lines 3-15) Terada does not disclose the combination of water soluble films and a drug compound. There is no suggestion to combine the disclosure of Terada with the disclosure of Fuchs to arrive at the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Thus, all the claims are allowable over these references.

In view of the above discussion and amendment, it is respectfully submitted that the present application is in condition for allowance. Therefore, an early reconsideration and allowance are respectfully requested.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned would appreciate the opportunity to do so.

Respectfully submitted,

Date: October 16, 2002

By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 12 has been deleted.

The claims have been amended as follows:

1. (Twice Amended) A soluble film preparation for oral administration comprising a drug, an edible polymer and a monosaccharide or a oligosaccharide, wherein film is obtained by spreading and drying and has an elution rate of more than about 50% per 10 minutes and wherein the drug is a compound enhanced in internal absorption by forming a solid solution with the edible polymer.

4. (Twice Amended) The soluble film preparation according to claim 1~~3~~, in which the compound is at least one of nilvadipine~~.~~, nifedipine, phenytoin, chloramphenicol, griseofulvin, or sulfamethizole.

8. (Twice Amended) The soluble film preparation according to claim 1, in which the oligosaccharide is reducing maltose starch syrup .

11. (Twice Amended) The soluble film preparation according to claim 1~~0~~, in which the compound is nilvadipine, the additional edible polymer is hydroxypropyl cellulose, and the starch syrup is reducing maltose starch syrup.